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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/345,581 09/16/92 WEINBERG

J 95499/00646

EXAMINER

DAVENPORT, A

ART UNIT PAPER NUMBER

1811

DATE MAILED: 11/16/92

CUSHMAN, DARBY & CUSHMAN
9TH FLOOR
1100 NEW YORK AVE., N.W.
WASHINGTON, DC 20005-3918

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☐ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice re Patent Drawing, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, Form PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐ _____

Part II SUMMARY OF ACTION

- ☒ Claims 1-5 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- ☐ Claims _____ have been cancelled.
- ☐ Claims _____ are allowed.
- ☒ Claims 1-5 are rejected.
- ☐ Claims _____ are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.
- ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
- ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

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References cited in the specification have been considered in part. However, if applicant desires specific references to be made of record then applicant must provide copies of the most pertinent references and comply with the conditions of 37 CFR 1.56 and 1.97-1.99, including a completed PTO-1449.

The disclosure is objected to because of the following informalities: there are several references which contain incomplete citations, for example page 3, line 22, the Immunology Today reference is incomplete, page 4, line 7, the J. Cell Biol. reference is incomplete. Appropriate review and correction of the entire specification are required.

The use of the trade mark FACS STAR PLUS has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by

the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The specification provides no probative evidence to show the claimed utility of the method in suppressing T cell activation, inhibiting CD44-monocyte mediated IL-1 release or treating inflammation with CD44 protein, peptides or derivatives. Applicant has shown that CD44 protein is present in synovium of patients, however, the correlation between administration of CD44 protein, peptides or derivatives and inhibiting IL-1 release, suppressing T cell activation and inhibiting inflammation is unclear. Were peptides or derivatives ever administered in vivo or in vitro to show inhibition of cell adhesion, IL-1 release or reduction of inflammation? Were monocytes ever depleted from the experimental cell population to determine the role of monocytes in CD44-mediated cell adhesion or IL-1 release? Applicant presents data on suppression of T cell activation in Table 6. This is unclear because there appears to be little effect of CD44-liposomes on the suppression of CD2 mediated T cell activation. What was the effect of CD44 without liposomes? It is unclear whether the effect on T cell activation was due to CD44 or solely to liposomes. Because of the aforementioned deficiencies in the specification and lack of guidance presented,

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it would require undue experimentation to practice the invention.

Claims 1-3 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-3 are rejected under 35 U.S.C. § 103 as being unpatentable over Haynes et al. (1989) in view of St. John et al.

Haynes et al. describe the role of leukocyte adhesion molecules (CD44) in regulating T cell activation, monocyte mediated Il-1 release and in inflammation (page 173) during lymphocyte trafficking and homing to specific tissues. Haynes et al. do not describe peptides or derivatives of the adhesion molecule. However, St. John et al. describe the sequence of the lymphocyte adhesion molecule (figure 4) and polypeptides which may be included in therapeutic preparations of the adhesion

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molecule effective in modulating autoimmune disease states such as rheumatoid arthritis, chronic site specific inflammatory conditions and adhesion-mediated entry of circulating lymphocytes into peripheral lymph nodes, mucosal organs and inflamed synovia (column 4, lines 18-55). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Haynes et al. on the role of CD44 adhesion molecule with the teachings of St. John et al. on polypeptides and other epitopes useful in therapeutic compositions of the leucocyte adhesion molecule with the expectation of a method of suppressing T cell activation in an animal, inhibiting CD44 monocyte-mediated IL-1 release and treating inflammation with the further expectation, in the absence of a showing of unexpected results, that the method would be effective in reducing inflammation, inhibiting IL-1 release and suppressing T cell activation in an animal.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 4 and 5 are rejected under 35 U.S.C. § 101 because the invention as disclosed is inoperative and therefore lacks utility.

Applicant's invention is directed to a method of preventing and treating HIV infection in an individual. Applicant's fail to

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present data demonstrating the in vivo utility of the claimed compounds nor does he show the utility of his compounds in an art accepted model correlated with human utility. Furthermore, the claims as written are of such incredible utility as to create a strong presumption of inoperativeness that can only be overcome by very clear objective evidence. See Ex parte Heicklen, 16 USPQ 2d 1463. There has been no effective means established that would prevent the infection of HIV. There have only been one or two limited treatments accepted in the HIV area. It is unbelievable on its face that applicant's have found an effective prevention or treatment of HIV infection in the absence of overwhelming evidence. For, Congress did not intend that a patent be granted on a chemical compound, or a process for its production, whose sole "utility" consists of its potential role as an object of use testing. See Brenner, Comr. Pats V. Manson (USSC 1966) 383 US 519, 148 USPQ 689. For these reasons the claims have been rejected as inoperative and therefore lacking utility. See In re Ferens (CCPA 1969) 417 F2d 1072, 163 USPQ 609; Ex parte Moore et al. (POBA 1960) 128 USPQ 8; In re Hozumi et al., (Comr. Dec. 1985) 226 USPQ 353; and Rhone-Poulenc S.A. v. Dann (CA4 1974) 507 F2d 261, 184 USPQ 196.

Claims 1-3 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-3 of copending application Serial No. 07/669730. This is a provisional double patenting rejection since the conflicting claims have not in fact

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been patented.

Claims 1-3, directed to the same invention as that of claims 1-3 of commonly assigned Application SN. 07/669730. The issue of priority under 35 U.S.C. § 102(g) and possibly 35 U.S.C. § 102(f) of this single invention must be resolved.

Since the Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see M.P.E.P. § 1101.01(b)), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. § 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of the application.

Claims 1-3 are provisionally rejected under 35 U.S.C. § 102(e) as being anticipated by copending application Serial No. 07/669730.

Copending application Serial No. 07/669730 has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. § 102(e) if patented. This provisional rejection under 35 U.S.C. § 102(e) is based upon a presumption of future patenting of the conflicting copending application.

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This provisional rejection under section 102(e) might be overcome either by a showing under 37 C.F.R. § 1.132 that any unclaimed invention disclosed in the copending application was derived from the inventor of this application and is thus not the invention "by another", or by a showing of a date of invention of any unclaimed subject matter prior to the effective U.S. filing date of the copending application under 37 C.F.R. § 1.131.

This is a continuation of applicant's earlier application S.N. 07/682518. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See M.P.E.P. § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Avis Davenport whose telephone number is (703) 308-4002.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

[Signature]
MERRELL C. CASHION, JR.
SUPERVISORY PATENT EXAMINER
GROUP 180

AND
Avis Davenport
November 16, 1992